

## **II. REMARKS**

Claims 56, 57, 62 and 91 to 94 are pending in the subject application, were examined and stand variously rejected. Claims 1 to 55, 58 to 61 and 63 to 90 have been previously canceled. By this Amendment, claims 56, 57 and 90 have been amended. Applicants' amendment of the claims as previously presented are made without prejudice to Applicants' right to pursue the same or similar subject matter in a related application. The amendment of the claims are not intended to be a dedication to the public of the subject matter of the claims as previously presented.

The claim amendments do not raise an issue of new matter. Support for the amendments is found in the application papers on page 8, line 6 to page 17, line 5; page 21, line 1 to page 24, line 12 and pages 63 to 75. Entry of these amendments is respectfully requested.

This Amendment changes and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

In view of the preceding amendments and the remarks which follow, reconsideration and withdrawal of the rejections is respectfully requested. After amending the claims as set forth above, claims 56, 57, 62 and 91-94 are presently pending and under examination.

### **35 U.S.C. § 112, First Paragraph**

Claims 56, 57, 62 and 91 to 92 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office states that claims 56 and 57 are directed to methods of "inhibiting" and "treating," respectively, wherein the particular disease to be inhibited or treated has been specified as a list of disease cell types, the cell types being breast, non-small cell lung, rectal, head and neck, stomach, pancreatic, colon, liver, gastric and ovarian. The Office alleges that the organ-related cell types in this list only may meet the written description requirement when the cell is derived from breast, colon or lung in view of the instant disclosures wherein these tissues have been tested. The Office argues that, for the other listed types of neoplastic cell types, the written description requirement allegedly has not been met.

Applicants respectfully traverse and submit that the written description requirement of 35 U.S.C. § 112, first paragraph has been met by Applicants' specification for the reasons of record. Prior to the above amendment of the claims, Applicants' claims recited the cancer types shown to overexpress TS and which therefore share a common mechanism of action to activate the compounds (also previously as claimed). In sum, based on the overexpression of TS in cancer cell types, Applicants have objective evidence that the claimed compounds, having a common structure, would be active against the claimed cancers which commonly overexpress TS. There is no suggestion on the record from Applicants that one or more cancer cell types migrate and form the basis of another cancer, e.g., head and neck from breast cancer. (See Examiner's reference to Smith et al. on page 3 of the outstanding Office Action.

However, in a sincere effort to advance examination and without conceding the correctness of the Examiner's position, the composition of matter claims have been amended as suggested by the Examiner. The claims directed to methods to inhibit the growth of cancer cells and to treat cancer have been amended to recite breast, lung and colon cancers, also as suggested by the Office. Accordingly, in view of the preceding amendments and the preceding remarks, reconsideration and withdrawal of the rejection is respectfully requested.

The Office states that claims 62, 91 and 92 are directed to compounds which have been tested and to other compounds encompassed by the terminology at lines 40-43 wherein all manner of stereoisomers are encompassed. The Office admits that Applicants clearly have support for the D-ribosyl compounds, esters, ethers and salts, but alleges that there is no support for the remainder of the alternatives either in the area of synthesis or the area of pharmacological activity.

As noted above, without conceding the correctness of the Examiner's position and in a sincere effort to advance examination, the composition of matter claims 62, 91 and 92 have been amended to the D-ribosyl compounds. In view of this amendment, reconsideration and withdrawal of this ground for rejection is respectfully requested.

Claims 56 and 57 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabled for certain breast neoplasms, colon neoplasms and lung neoplasms, allegedly does not reasonably provide enablement for any of the other varieties of neoplasms as currently listed in claims 56 and 57. The Office alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Office argues that the fundamental issue is whether practicing the full scope of the instant invention is possible without undue experimentation. The Office cites *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988)) in its argument that allegedly undue experimentation is necessary practicing the full scope of the claimed invention.

The Office alleges that the breadth of the claims as defined by the lists of neoplastic cell types is excessively broad because said term reads on multiple different disease conditions including all varieties of neoplasms (cancer cells). The Office states that claims 93 and 94 are limited to generic classes of neoplastic cell types including enabled specific neoplastic diseases.

The Office argues that the nature of the invention as described in the specific examples is allegedly limited to showing that a single compound, a phosphoramidated derivative of 5-bromovinylated 2'-deoxyuridine nucleoside is much more effective than the non-phosphoramidated BVDU base compound in treating certain specific neoplastic diseases, human breast carcinoma, a specific strain of lung cancer and human colon carcinoma in particular.

The Office also argues that the state of the prior art; the extensive prior art of record, as the Examiner has reviewed and understood, allegedly does not anticipate or render obvious the treatment of carcinomas with a phosphoramidated BVDU.

The Office states that the level of one of ordinary skill is defined by the need to understand organic synthesis and the testing of compounds in *in vitro* cell culture. The Office goes on to state that the level of predictability in the art is low because allegedly only two closely related neoplastic disease conditions have been shown to be effectively inhibited by a phosphoramidated BVDU compound. The Office argues that the amount of direction provided by the inventor is allegedly limited to showing how to make and administer a single phosphoramidated BVDU compound to cause inhibition of three neoplastic disease conditions.

The Office states that the existence of working examples is allegedly limited to a single compound administered to cells in *in vitro* culture infected by three neoplasms, all of which the Office assumes are probably carcinomas. The Office concludes that the quantity of experimentation needed to make or use the invention based on the content of the disclosure would be excessive because allegedly the disclosure does not describe how to effectively treat anything other than carcinoma in human breast, human lung and human colon tissue.

As noted above, without conceding the correctness of the Examiner's position and in a sincere effort to advance examination, claims 56 and 57 have been amended to recite only those cancers specifically exemplified by Applicants' specification. In view

of these amendments, reconsideration and withdrawal of the rejection is respectfully requested.

### **Claim Informalities**

The Office objects to claim 62 for alleged informalities. The offending language has been removed from the claim thereby obviating this ground for objection.

### **Obviousness-Type Double Patenting**

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-12 of U.S. Patent No. 6,495,553 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 36-39 of U.S. Patent No. 6,339,151 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-7 of U.S. Patent No. 6,245,750 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 7-30 and 37-40 of co-pending Application No. 10/119,927 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1 and 53-83 of co-pending Application No. 10/681,418 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-10 of U.S. Patent No. 6,683,061 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-19 of co-pending Application No. 10/048,033 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 15-18, 21-23 and 27-50 of co-pending Application No. 09/789,226 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-53 of co-pending Application No. 11/034,036 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 93 and 94 as allegedly unpatentable over claims 1 and 2 of U.S. Patent No. 7,138,388 for the reasons of record.

The Office maintains the obviousness-type double patenting rejection of claims 56, 57, 62 and 91 to 94 as allegedly unpatentable over claims 1-20 of co-pending Application No. 11/516,457 for the reasons of record.

With the exception of U.S. Serial No.: 10/048,033, in which the allegedly conflicting claims have now been canceled, and without conceding the correctness of the Office's position and to advance allowance, attached to this reply is a terminal disclaimer . The Office is authorized to charge the fee to record this terminal disclaimer. In view of the filing of this paper and payment of the fee, Applicant respectfully requests reconsideration and withdrawal of the non-statutory obviousness-type double patenting rejections.

Furthermore, the Office states that one or more of claims 56, 57, 62 and 91-94 of the instant application allegedly conflict with claims 7-30 and 37-40 of Application No. 10/119,927, claims 1 and 53-83 of co-pending Application No. 10/681,418, claims 1-36 of co-pending Application No. 11/034,036, claims 1-20 of co-pending Application No.

11/516,457, claims 1-19 of co-pending Application No. 10/048,033 and claims 15-18, 21-23 and 27-50 of co-pending Application No. 09/789,226.

The Office cites 37 CFR § 1.78(b) and states that when two or more applications filed by the same applicant contain conflicting claims, that elimination of such claims from all but one of application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. The Office requests that Applicants either cancel the allegedly conflicting claims from all but one application, or maintain a clear line of demarcation between the applications.

Applicants' undersigned attorney acknowledges the Examiner's attention to the allegedly conflicting claims in the above-noted applications. Applicants' attorney has reviewed the applications and believes that recent amendments have removed any overlapping subject matter of the present application and U.S. Serial Nos.: 10/119,927; 10/048,033; 10/681,418 and 11/516,457; . Applicants will defer amendment of the claims in U.S. Serial Nos.: 11/034,036 and 09/789,226 to remove allegedly conflicting subject matter until a later date.

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### III. CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By Antoinette F. Konski

FOLEY & LARDNER LLP  
Customer Number: 38706  
Telephone: (650) 251-1129  
Facsimile: (650) 856-3710

Antoinette F. Konski  
Attorney for Applicant  
Registration No. 34,202